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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,814	09/04/2002	Andrew Austen Mortlock	ASZD-P01-599	2356
28120	7590	04/14/2004	EXAMINER	
ROPE & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER

1624

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,814	Applicant(s) MORTLOCK ET AL.	
	Examiner Tamthom N. Truong	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03-21-02</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's preliminary amendment of 09-04th-02 has been entered.

Specification

1. The disclosure is objected to because of the following informalities: Where parentheses are used in the specification, several places do not have a 'closing parenthesis' (e.g., page 7, items #2-4, item 9, etc.). The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Use Claims:** Claims 1-18, and 31 provide for the use of a compound of formulae (I), (II), (IIC), (VI), and (VIC), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

3. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claims 1, 15, 16, 19-24, and 28-30 recite the limitation of “*ester, amide or prodrug thereof*” which includes the narrow limitations of “*ester*”, and “*amide*” as well as the broad limitation of “*prodrug*”.
- b. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).
- c. Claim 5, item #18 recites the limitation of “*particularly alkyl esters thereof*” which indicates a narrow limitation followed the broad limitation of “*carboxy*”. Such language renders the claim indefinite for the reason set forth above.

d. Claim 8 lacks antecedent basis because it recites “ R^2 or R^3 comprises a chain of at least 3...heteroatoms...” which is not recited in any of the preceding claims.

e. Claim 10 recites R^{15} to include a “methylene group directly adjacent X^1 ”, which renders the claim indefinite because “methylene” is a divalent group while R^{15} is a terminal group. Thus, it is unclear what the terminal group for R^{15} is.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Use claims: Claims 1-18, and 31 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Utility -- Claim Rejections - 35 USC § 112 and 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-18, 28, and 31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specifically asserted utility or a well established utility.

A revised utility guideline requires that utilities must be specific, substantial, and credible. By specific, said guideline calls for a particular disorder or disease. In the case of cancer treatment, a specific type of cancer must be indicated. By substantial, said guideline requires that utilities must define a “real world” use, and must not constitute further research to identify or reasonably confirm a “real world” context of use.

In the instant case, said claims call for “*the inhibition of aurora 2 kinase*” which is not specific, and not substantial as the specification does not appear to relate a **specific disorder** to such an inhibition. Furthermore, “*the inhibition of aurora 2 kinase*” is not a well known method, and thus requires extensive further research. Note, the specification only provides *in-vitro* assays for the compound’s activity, but it does not correlate said activity to the treatment of any disorder by *in-vivo* testing. Therefore, the method or use as claimed does not have a “real world” use, and thus requires further research to reasonably confirm a “real world” context of use.

Because applicant has not disclosed any specific and substantial utility for the claimed invention, credibility will not be assessed. See *Brenner v. Manson*, 148 USPQ 689, and *In re Zeigler*, 26 USPQ 2d 1600, 1603 (Fed. Cir. 1996).

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18, 28, and 31 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specifically asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Objections

8. Claims 4 and 5 are also objected to because of the following informalities: a closing parenthesis is omitted in said claims (e.g., claim 4, items #2-4, and item #22; also claim 5, items 5 and 22). Appropriate correction is required.

9. Claims 12, 13, 21, 23, 24, 27, 29, and 30 are also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the other claims the alternative only. See MPEP § 608.01(n). In this instance, said claims are improper multiple dependent for the following reasons:

- f. claims 12 and 13 depend on any one of the preceding claims, but at the same time refer to claim 1 for the definition(s) of variable(s). Claim 21 depends on both claims 1 and 15 at the same time.
- g. Claim 23 depends on claims 1, any one of claims 1-6, and 17 at the same time.
- h. Claim 24 depends on claims 23 and 18 at the same time.

- i. Claim 27 depends on the set of claims 19-26, and the set of claims 18-26 at the same time.
- j. Claims 29 and 30 depend on the set of claims 19, 20, and 23 as well as the set of claims 21, 22, and 24.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 23-25, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by **Hudson et. al.** (WO 96/09294 – cited on IDS). On page 12, Hudson et. al. disclose two compounds of “4-(4-Anilinocarbonylanilino)-6,7-dimethoxyquinazoline”, and “6,7-Dimethoxy-4-(4-phenyl-sulfinylanilino)quinazoline which read on the compounds of the following claims:

- a. Claim 23 wherein:
 - i. X is NH, and Y is C or S(O);
 - ii. R¹, R⁴, R⁶, R⁷, and R⁸ are all hydrogen;
 - iii. R⁶⁵ is -NR¹⁰R¹¹ (with one of R¹⁰ and R¹¹ as hydrogen while the other as a hydrocarbyl group (i.e., phenyl));

- iv. R^{68} and R^{69} are both $-X^1R^{15}$ (with X^1 as $-O-$, and R^{15} as an alkyl group – i.e., together $-X^1R^{15}$ forms a methoxy group).
 - b. Claim 24 wherein:
 - i. X is NH , and Y is C or $S(O)$;
 - ii. R^1 , R^4 , R^7 , and R^8 are all hydrogen;
 - iii. R^{65} is $-NR^{10}R^{11}$ (with one of R^{10} and R^{11} as hydrogen while the other as a hydrocarbyl group (i.e., phenyl));
 - iv. R^{68} and R^{69} are both $-X^1R^{15}$ (with X^1 as $-O-$, and R^{15} as an alkyl group – i.e., together $-X^1R^{15}$ forms a methoxy group).
 - c. Claim 25 wherein X is NH .
 - d. Claims 29 and 30 since they depend on claims 23 and 24.
12. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by **Hudson et. al.** (WO'294). Claim 22 of WO'294 recites a process that reads on that of the instant claim 27. Note, formula (II) of the reference corresponds to formula (VIII'), and the leaving group L is equivalent to the instant R^{85} . Likewise, formula (III) of the reference corresponds to formula (IX'), and the group $-YH$ is equivalent to the instant group $-XH$.

Because the teaching of Hudson et. al. reads on all limitations of the above claims, it anticipates them.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-T (~10 am ~ 8:30 pm) starting from February 22nd, 2004.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

April 8, 2004



MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
APR 12 2004